OCT - 3 2011

K111606

SECTION II. 510(K) SUMMARY

A. Device Name

Proprietary Name	Pinnacle Precision Access System
Classification Name	Catheter Introducer (as per 870.1340)
Common Name	Introducer Sheath
Product Code	DYB

B. Intended Use

The Pinnacle Precision Access System is used to facilitate placing a catheter through the skin into a vein or artery.

The Entry Needle is an accessory device which is used to gain access to the vein or artery, for placement of the Mini Guide Wire.

The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery.

C. Device Description

The Pinnacle Precision Access System consists of an introducer sheath and a dilator which are packaged together with a metallic entry needle, a mini guide wire and a guide wire inserter, prior to sterilization. The Pinnacle Precision Access System is used to facilitate placing a catheter through the skin into a vein or artery. The sheath and dilator contain bismuth, making these devices visible under fluoroscopy

The entry needle (cannula) is an accessory device which is used to gain access to the vein or artery for placement of the mini guide wire.

The mini guide wire is an accessory device which is used for placement of the sheath and dilator into the vein or artery. The mini guide wire is offered in two versions, a stainless steel (spring coil) model and a Palladium tipped Nitinol model.

A guide wire inserter is also provided to assist in insertion of the mini guide wire into the cannula.

D. Principle of Operation / Technology

The Pinnacle Precision Access System and its accessories are operated manually or by a manual process.

The mini guide wire is inserted through a cannula placed in the patient's blood vessel. A guide wire inserter is provided to assist in insertion of the mini guide wire into the cannula. Following guide wire insertion, the cannula is removed and the sheath and dilator are then inserted over the mini guide wire and into the blood vessel. The mini guide wire is then withdrawn from the vessel. The dilator maintains the integrity of the Sheath and dilates the blood vessel during insertion. Once the sheath is situated in the vessel, the dilator is removed and an appropriate catheter can then be inserted through the sheath.

E. Design / Materials and Comparison to Predicate Devices

The primary components of the Pinnacle Precision Access System in this submission (the Sheath and Dilator) are unchanged from those of the Radifocus Introducer II predicate device (K954234). The Pinnacle Precision Access System differs from the Radifocus Introducer II predicate device in the addition of the metallic entry needle and the optional Nitinol Mini Guide Wire. A metallic entry needle and Nitinol Mini Guide Wire are included in the Glidesheath predicate device (K102008).

The Pinnacle Precision Access System submitted in this 510(k), the Radifocus Introducer II (K954234) and the Glidesheath (K102008) have similar components which function in the same manner. Material differences between the devices, as shown in the following table, do not raise any new issues of safety and effectiveness.

Component	Radifocus Introducer II (K954234)	Glidesheath (K102008)	Pinnacle Precision Access System
Wire	Stainless Steel	Nitinol w/Palladium distal coil	Stainless Steel or Nitinol w/Palladium distal coil
Needle	N/A	Stainless Steel	Stainless Steel
Needle Hub	N/A	Styrene-Butadiene copolymer	Styrene-Butadiene copolymer
Protective Sleeve	N/A	Polypropylene	Polypropylene
Dilator Tubing	Polypropylene w/Bismuth subcarbonate	Polypropylene w/Bismuth subcarbonate	Polypropylene w/Bismuth subcarbonate
Dilator Stiffener	N/A	N/A	Stainless Steel (optional on 4Fr and 5Fr)

Dilator Caulking Pin	Stainless Steel	Stainless Steel	Stainless Steel
Dilator Hub	Polypropylene	Polypropylene	Polypropylene
Sheath Tubing	ETFE w/15% BiO3, w/2% TiO2	ETFE w/15% BiO3, w/2% TiO2	ETFE w/15% BiO3, w/2% TiO2
Sheath Caulking Pin	Stainless Steel	Stainless Steel	Stainless Steel
Sheath Housing	Polypropylene	Polypropylene	Polypropylene
Sheath Support	Styrene elastomer	Styrene elastomer	Styrene elastomer
Valve	Silicone rubber	Silicone rubber	Silicone rubber
Cap	Polypropylene	Polypropylene	Polypropylene
Sidetube	Polybutadiene	Polybutadiene	Polybutadiene
3WSC	Polycarbonate, Polyethylene, Polypropylene	Polycarbonate, Polyethylene, Polypropylene	Polycarbonate, Polyethylene, Polypropylene
Guide wire inserter	Polypropylene	Polypropylene	Polypropylene

F. Specifications and Comparison to Predicate Devices

The Pinnacle Precision Access System submitted in this 510(k), the Radifocus Introducer II (K954234) and the Glidesheath (K102008) have similar device specifications. Differences in specifications between the devices do not raise any new issues of safety and effectiveness.

	Radifocus Introducer II (K954234)	Glidesheath (K102008)	Pinnacle Precision Access System
Sheath Sizes	4Fr - 11Fr	5Fr and 6Fr	4Fr through 8Fr
Sheath Length	5cm - 100cm	10 cm	10 cm
Sheath Coating	Silicone	Hydrophilic	Silicone
Dilator Length	6cm - 110cm	15.5 cm	15.5cm or 16.0cm
Guide Wire OD	.021" - .038"	.021"	.021"
Guide Wire Length	40cm – 100cm	45cm	45cm
Entry Needle: Size	N/A	21G 1.5"	21G/19G 2.75"

G. Performance

The Pinnacle Precision Access System successfully passed all of the following performance tests:

Pinnacle Precision Access System Performance Testing	
Needle:	Needle surface free from defects
	Needle OD
	Needle length
	Needle ID
	Needle hub conical entry angle
	Bevel indicator visibility
	Bevel indicator position
	Needle to hub joint strength
	Gauge luer taper
	Liquid leakage from fitting assembly under pressure
	Air leakage into the fitting assembly during aspiration
	Separation force of fitting assembly
	Unscrewing torque of fitting assembly
	Ease of assembly
	Resistance to overriding
	Stress cracking
	Tip penetration through thin film
	Corrosion resistance
Guidewires:	Guidewire surface free from defects
	Tip buckling test
	Test for resistance of guidewires to damage by flexing
	Test for fracture of guidewires
	Test for distal tip retention and proximal end retention
	Guidewire OD
	Guidewire length
	Corrosion resistance
	Radiopacity
Dilator:	Dilator surface free from defects
	Dilator tip ID
	Dilator to hub joint strength
	Dilator length
	Dilator OD at sheath tip interface
	Dilator hub to sheath hub snap fit strength
	Hypotube length
	Hypotube to hub joint strength
	Hypotube fall-out
	Wire passage

	Corrosion resistance (hypotube)
Sheath:	Sheath surface free from defects
	Sheath tip ID
	Sheath length
	Sheath tip cracks
	Radiopacity
Simulated Use:	System use in anatomical model
	Dilator and sheath tip penetration

H. Biocompatibility and Sterilization

Biocompatibility testing was conducted in accordance with the FDA General Program memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".

The Pinnacle Precision Access System is classified as an Externally Communicating Device, Circulating Blood, Prolonged Contact (up to 30 days), the same as the Radifocus Introducer II Sheath predicate device. Biocompatibility of the Radifocus Introducer II Sheath, classified as Externally Communicating Device, Circulating Blood, Prolonged Contact (24 hours – 30 days) has been established under K954234. Differences in materials between the Pinnacle Precision Access System and the Radifocus Introducer II Sheath affect only those portions of the system that contact the patient for a short period of time (less than 24 hours). Therefore, the full battery of biocompatibility tests was performed on the whole device for Externally Communicating Devices, Circulating Blood, Limited Contact (up to 24 hours).

Testing was performed on the worse case configuration of the system: Introducer sheath with stiffener, stainless steel guide wire and echogenic step needle. Results are presented in the following table.

Biocompatibility Testing on non-aged, 2x EO sterile Pinnacle Precision Access System		
Test	Standard	Result
Physicochemical profile	USP	Meets requirements
Cytotoxicity	ISO 10993-5	Not considered to have cytotoxic potential
Hemolysis	ASTM F756	Non-hemolytic
In vitro Hemocompatibility Assay	ISO 10993-4	Pass
Thrombogenicity Study in Dogs	ISO 10993-4	Thrombosis was not considered significant
Complement Activation	ISO 10993-4	Meets requirements
Unactivated Partial Thromboplastin time	ISO 10993-4	Meets requirements
Prothrombin Time	ISO 10993-4	No adverse effect on the prothrombin time of human plasma
Sensitization	ISO 10993-10	Meets requirements
Intracutaneous Reactivity	ISO 10993-10	Meets requirements
Acute Systemic Toxicity	ISO 10993-11	Negative
Pyrogenicity	ISO 10993-11	Meets requirements
Genotoxicity	ISO 10993-3	Not considered to be mutagenic

Alkalinity/acidity and extractables testing was performed per ISO 7864: Sterile Hypodermic Needles for Single Use on 2x EO sterile, non-aged needles.

Pinnacle Precision Access System- Echogenic Taper Needle (non-aged, 2xEO sterile)		
Test	Standard	Results
Analysis of Metals in Extract by Inductively Coupled Plasma Mass Spectrometry	(ICP-MS) Per ISO 7864	Meets requirements

Limited screening tests were conducted on accelerated aged, 2x EO sterile devices to demonstrate that aging does not affect the device's biocompatibility.

Biocompatibility Testing on aged 2x EO sterile Pinnacle Precision Access System		
Test	Standard	Results
Physicochemical profile	USP	Meets requirements
Cytotoxicity	ISO 10993-5	Not considered to have cytotoxic potential
Hemolysis	ASTM F756	Non-hemolytic

Sterilization conditions have been validated according to ANSI / AAMI / ISO 11135, *Sterilization of Health Care Products– Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices,* to provide a Sterility Assurance Level (SAL) of 10-6.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals will meet requirements for limited exposure devices (contact up to 24 hours) prior to use, based on ISO 10993-7, Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization residuals. Residual EO will not exceed 4 mg per device and residual ECH will not exceed 9 mg per device.

The Pinnacle Precision Access System is certified to be non-pyrogenic in the unopened and undamaged package. Kinetic Turbidimetric Limulus Amebocyte Lysate (LAL) test is performed on each lot of production accordance to the United States Pharmacopoeia (USP) <85> Bacterial Endotoxins Test. Validation was performed in accordance with FDA published "Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices"; 1987.

I. Substantial Equivalence

The performance of the Pinnacle Precision Access System in this submission is substantially equivalent to the performance of the predicate devices. The equivalence was shown through comparison of component materials and specifications, performance and biocompatibility testing and sterilization validation.

The Pinnacle Precision Access System is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the predicate devices the Radifocus Introducer II (K954234) and the Glidesheath (K102008). Differences between the devices do not raise any significant issues of safety or effectiveness.

J. Submitter Information

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Date Prepared:	June 8, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Terumo Medical Corporation
c/o Mr. Daniel R. Plonski, RAC
Regulatory Affairs Specialist
950 Elkton Blvd.
Elkton, MD 21921

OCT - 3 2011

Re: K111606
Trade/Device Name: Pinnacle Precision Access System™
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 23, 2011
Received: September 26, 2011

Dear Mr. Plonski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111606

Device Name: Pinnacle Precision Access System™

Indications For Use:

The Pinnacle Precision Access System is used to facilitate placing a catheter through the skin into a vein or artery.

The Entry Needle is an accessory device which is used to gain access to the vein or artery, for placement of the Mini Guide Wire.

The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111606